PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of
Haffner et al.

Group Art Unit: 1626

Filed: 8 August 2003

Examiner: R. Anderson

Serial No.: 10/637,190

November 4, 2004

Attorney Docket No: PU3616US2

For: USE OF FXR LIGANDS

The Honorable Commissioner of
Patents and Trademarks
Washington, DC 20231

APPEAL BRIEF

TABLE OF CONTENTS

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APPEAL BRIEF

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed concurrently herewith.

REAL PARTY IN INTEREST

The subject application is owned by SmithKline Beecham, a corporation doing business as GlaxoSmithKline, and having principal places of business in Philadelphia, PA and Research Triangle Park, NC.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

Claims 16 and 36 are pending in this application. The final rejection of Claims 16 and 36 as non-enabled is appealled.

The application was originally filed with claims 1-35. Claims 1-11, 14, 17-19 and 22-35 were cancelled by preliminary amendment. Remaining claims 12, 13, 15, 16, 20 and 21 were subject to a restriction requirement. Appellants elected claims 16 and 20, and added new claim 36, in response to the restriction requirement. Non-elected claims, and claim 20, were subsequently canceled, leaving claims 16 and 36 pending.

STATUS OF AMENDMENTS

The Final Office Action dated 1 October 2004 rejects claims 16 and 36 under 35 U.S.C. §112, first paragraph. No amendment has been filed subsequent to the Final Office Action.

SUMMARY OF THE INVENTION

The present invention relates to the administration of non-steroidal FXR agonist compounds having a defined formula, in order to lower serum triglyceride levels. See e.g., the specification at Example 5 (page 25 – 28), and particularly page 28, lines 4-10.

ISSUES

Whether one must enable the treatment of multiple diseases related to elevated serum triglyceride levels, where the claims recite a method of lowering serum triglycerides in a mammal in need thereof by administering a class of compounds defined by structure and function.

GROUPING OF CLAIMS

Claims 16 and 36 stand or fall together.

THE EXAMINER'S RATIONALE

Claims 16 and 36 stand rejected as non-enabled (35 USC §112, first paragraph). Claim 36, the sole independent claim, recites a " method of lowering serum triglycerides in a mammal, comprising administering to a mammal in need thereof an effective serum triglyceride lowering amount of a nonsteroidal agonist for Farnesoid X Receptor of the following formula: [formula omitted]".

The Examiner states that the claims encompass "treatment of any disease characterized by lowered serum triglycerides"[1], argues that the specification provides enablement "only . . . for the lowering of serum triglycerides for the treatment of atherosclerosis and not for the treatment of any disease or disorder . . ."[2], and concludes that "the quantity of experimentation needed is undue . . . [o]ne of skill in the art would need to determine what diseases characterized by the modification of lipid levels would benefit from lowered serum triglycerides and . . . what compounds of the elected invention would provide treatment of what, if any, disease".[3]

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[1] Final Office Action, page 6, second paragraph.
[2] Final Office Action, page 3, line 5-7.
[3] Final Office Action, page 6, third paragraph.

ARGUMENT

I. The claimed invention has patentable utility.

The present claims are not rejected under 35 USC 101 as lacking patentable utility. However, as the utility and enablement requirements are intertwined, Appellants believe a brief discussion of utility is warranted.

As noted in the Manual of Patent Examination Procedure (MPEP) 2107.02 II(A): "[A] disclosure that identifies a particular biological activity of a compound and explains how that activity can be utilized in a particular therapeutic application of the compound does contain an assertion of specific and substantial utility for the invention."

As further noted in MPEP 2107.02(I): "It is common and sensible for an applicant to identify several specific utilities for an invention . . . . However, . . . an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 USC 101 and 35 USC 112; additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility." Citing *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful.").

Additionally, MPEP 2107.02 (I) states that "[Patent] Office personnel should also be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention. . . . Doing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to examination of that claim."

The present specification discloses that the compounds recited in the claim are FXR agonists, and that administration of such compounds can reduce serum triglyceride levels in mammals. The claims are directed to such a method, utilizing FXR agonists of a certain formula. The Examiner does not question the utility of the claimed invention, and states that the specification "is enabling for the method of lowering serum triglycerides in a mammal for the treatment of atherosclerosis".[4]

II. The present enablement rejection is based on improper claim scope.

The sole pending independent claim recites "[a] method of lowering serum triglycerides in a mammal". The pending claims do not recite the treatment of disease. However, the Examiner has rejected the claims as non-enabled, "because the specification while being enabling for the treatment of atherosclerosis does not reasonably provide enablement for the treatment of all disease mediated by modified lipid levels."[5] Appellants submit that this rejection is an improper "scope of enablement" rejection. The Federal Circuit has stated:

> The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

National Recovery Technologies v. Magnetic Separation Systems, 166 F.3d 1190, 49 USPQ2d 1671, 1675-76 (Fed. Cir. 1999).

However, in the present case the Examiner defines claim scope by reference to all potential therapeutic utilities mentioned in the specification. The Examiner states:

> (T)he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the specification coupled with information known in the art without undue experimentation and in making the determination of enablement, the examiner shall consider the original disclosure and all evidence in the record. . . . Applicants disclosure provides the use or utility of lowering serum triglycerides is for the treatment of any disease associated with the modulation of lipid levels. Appropriately, the Examiner has concluded that the instant disclosure coupled with the information known in the art only provides enablement for the lowering of serum triglycerides for the treatment of atherosclerosis and not for the treatment of any disease or disorder that applicant considers associated with the modulation of lipid levels.
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> ...
>
> (T)he specification . . . does not reasonably provide enablement for the treatment of all disease mediated by modified lipid levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.
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> Final Office Action, page 2-3 (underlining added).

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[4] Final Office Action, page 3, first full paragraph.
[5] Final Office Action, page 3-4, underlining added.

The Final Office Action states that the enablement rejection would be overcome by amending the claims to include only the method of lowering serum triglycerides for the treatment of atherosclerosis[6]. However, as stated in MPEP 2164, "(t)he invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application" (underlining added). As stated in MPEP 2164.01(a), a conclusion of lack of enablement means that, based on the evidence regarding each of the factors discussed in *In re Wands*, the specification at the time the application was filed, "would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation." (*In re Wands,* 858 F2d. 731, 8 USPQ2d 1400 (Fed. Cir. 1988), citing *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

Appellants submit that it is improper to require enablement of treating multiple *diseases*, where a claim recites a method of changing a physiological parameter, and that method (1) has patentable utility and (2) the Examiner has not established that undue experimentation would be required to carry out the claimed method.

III. Undue experimentation has not been established.

The initial burden of providing reasons why a supporting disclosure does not enable the claims rests with the examiner. *In re Marzocchi*, 439 F.2d 220,223, 169USPQ 367,368 (CCPA 1971). The examiner must establish that appellants have not provided sufficient disclosure, either through illustrative examples or terminology, for one skilled in the art to practice the invention as broadly claimed without having to resort to undue experimentation. See *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991).

Appellants submit that the Examiner has not established that undue experimentation is required to practice the claimed invention. The claims recite a method of lowering serum triglycerides. The Examiner has not set forth any reason to doubt that one skilled in the art could successfully make the compounds recited in the claim, and administer them in a manner that lowered serum triglycerides.

The Examiner recognizes that "(t)he nature of the invention in claims 16 and 36 is the lowering of serum triglycerides in a mammal". However, the Examiner then states that "(t)he claims fail to state the benefit of lowering serum triglycerides in a mammal (e.g., what disease/disorder is being treated or prevented?)".[7] Appellants submit that, where the utility of a claimed invention is established or apparent, there is no requirement that each claim recite "a benefit" of disease treatment. While realizing that each US patent is examined on its own merits, Appellants note that various US patents have issued claiming methods of altering serum cholesterol or lipid levels, where the claims do not recite the "benefit" of treating disease(s). (*See, e.g.,* US Patent No. 6,677,361; US Patent No. 6,713,057; US Patent No. 5,166,142.)

The Examiner's arguments regarding undue experimentation are focused on the unpredictability of disease therapy; she states that "the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of diseases characterized by modified lipid levels, whether the diseases included by this claim are affected by a compound which lowers serum triglycerides would affect the possible treatment of any disease."[8] The Examiner further states "(t)he nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities and which diseases would be affected by this activity. There is no absolute predictability even in view of the seemingly high level of skill in the art."[9]

As the court observed in *In re Brana,* 34 USPQ2d 1436, 1442 (Fed. Cir. 1995), it is possible that the Examiner "confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption."

Appellants submit that the Examiner has not met the burden of providing reasons why one skilled in the art would be unable to practice the claimed invention, a method of lowering serum triglycerides using compounds having a defined formula, without undue experimentation.

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[6] See Final Office Action, page 7, third paragraph.
[7] Final Office Action, page 4, second full paragraph (underlining added).
[8] Final Office Action, page 5, first paragraph (underlining added).
[9] Final Office Action, page 5, second paragraph (underlining added).

IV. Conclusion: The present claims are enabled

The Final Office Action quotes *Genentech v. Novo Nordisk A/S*, 108 F.3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997): "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."[10]

Applicants reject the characterization of the present claims as "vague intimations of general ideas". The pending claims recite the use of a specific class of compounds (defined by both structure and function) to lower a specific physiological parameter. Appellants believe that the Examiner has blurred the boundaries of utility, enablement, and claim scope, and has improperly required that the present invention provide an immediate "benefit" in the form of treatment of disease.

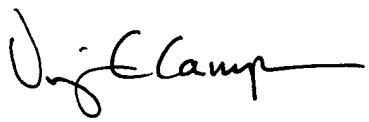
The burden of providing support for the present enablement rejection has not been met, and Appellants submit that the rejection of claims 16 and 36 under 35 U.S.C. §112, first paragraph, is in error.

[10] Final Office Action, page 7, second paragraph.

SUMMARY

On the entire record and in view of all the references, appellants submit that the Claims 16 and 36 are enabled. Accordingly, it is respectfully requested that the examiner's conclusions be reversed, and that this case be passed to issuance.

Respectfully submitted,

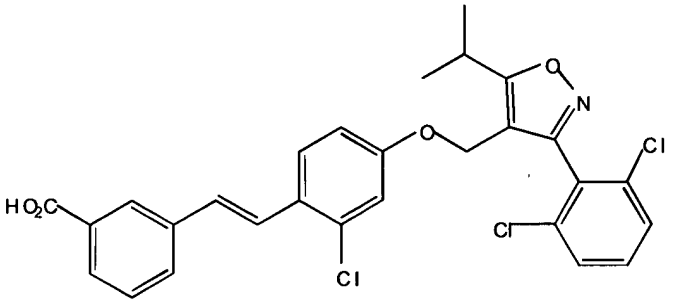


Virginia G. Campen
Registration No. 37,092

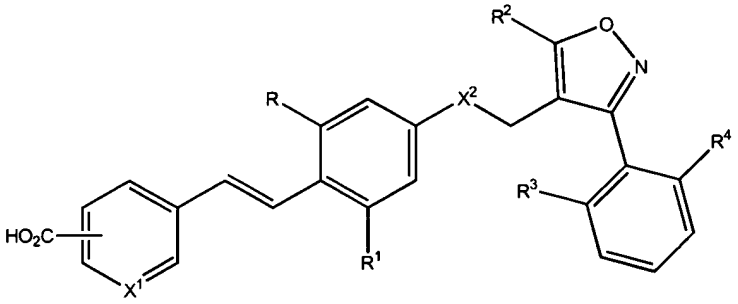
Docket No. PU3616US2

CLAIMS APPENDIX

16. (as amended) The method of claim 36 , wherein said FXR agonist has the following formula:



36. A method of lowering serum triglycerides in a mammal comprising administering to a mammal in need thereof an effective serum triglyceride lowering amount of a nonsteroidal agonist for Farnesoid X Receptor of the following formula:



wherein X^1 is CH, N; X^2 is O or NH; R and R^1 are independently H, lower alkyl, halogen, or CF_3; R^2 is lower alkyl; R^3 and R^4 are independently H, lower alkyl, halogen, CF_3, OH, O-alkyl, or O-polyhaloalkyl.

TABLE OF AUTHORITIES

CASES

STATUTES

Table of Authorities, Continued:

MANUAL OF PATENT EXAMINATION PROCEDURE (MPEP)

US PATENTS